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(21) International Application Number: PCT/DK92/00192 (22) International Filing Date: 19 June 1992 (19.06.92) (30) Priority data: 1208/91 21 June 1991 (21.06.91) DK (71) Applicant (for all designated States except US): NOVO NORDISK A/S [DK/DK]; Novo Alle, DK-2880 Bagsværd (DK). (72) Inventors; and (75) Inventors/Applicants (for US only) : KELDMANN, Troels [DK/DK]; Trongaardsvej 17 A, DK-2800 Lyngby (DK). KLITGAARD, Peter [DK/DK]; Johan Wilmanns Vej 31, I. t.h., DK-2800 Lyngby (DK).			(74) Common Representative: NOVO NORDISK A/S; Novo Alle, DK-2880 Bagsværd (DK). (81) Designated States: AU, BB, BG, BR, CA, CS, FI, HU, JP, KP, KR, LK, MG, MN, MW, NO, PL, RO, RU, SD, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG). Published With international search report.

A detailed cross-sectional diagram of a mechanical assembly, likely a valve or a seal, showing multiple layers and components. The assembly is symmetrical about a central vertical axis. The components are labeled with numbers 1 through 13:

- 1: A central vertical shaft or rod passing through the assembly.
- 2: A component on the right side, possibly a seal or a guide.
- 3: A component at the bottom right, possibly a base or a support.
- 4: A component on the right side, possibly a seal or a guide.
- 5: A component on the right side, possibly a seal or a guide.
- 6: A component on the left side, possibly a seal or a guide.
- 7: A component on the left side, possibly a seal or a guide.
- 8: A component on the left side, possibly a seal or a guide.
- 9: A component on the right side, possibly a seal or a guide.
- 10: A component on the right side, possibly a seal or a guide.
- 11: A component on the left side, possibly a seal or a guide.
- 12: A component at the bottom left, possibly a base or a support.
- 13: A component on the right side, possibly a seal or a guide.

A blood sampler comprises a cup shaped positioning part having a bottom (1) and a sidewall (2) and a sampling part having a bottom (4) and a sidewall (5). In the bottom (1) of the positioning part there is provided a central opening (9), which at the outer side of the cup is surrounded by a spacing ring (3). The sampling part has a needle (8) centrally through its bottom (4), which needle has at the outside of the sampling part a sharp end and inside the sampling part a sample collector (10). The sampling part fits displaceably into the positioning part with the sharp end of its needle (8) facing the opening (9) in the bottom (1) of this positioning part, but is by a snap lock (6, 7) releasably locked in a position with its bottom (4) near the upper edge of the positioning part. A cup shaped transparent cap (11) fits with its open end into the open end of the sampling part. In use the spacing ring (8) is pressed against the skin (12) by a finger (13) pressing the cap (11) until the snap lock (6, 7) releases and the sampling part passes into the positioning part with its needle (8) projecting through the opening (9) in the bottom (1) of this positioning part into the skin (12).

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BLOOD SAMPLER

The invention concerns a blood sampler for taking out small blood samples of the dimension a drop or so.

For many medical purposes it is necessary to take out small blood
5 samples to determine different blood parameters such as glucose content, coagulation time etc. For this purpose the skin of the patient is pierced by a needle or stiletto to provide a small wound from which a single drop of blood is made to bleed out. The blood drop may e.g. be placed on a piece of indicator paper directly as it is often the case when the patient himself frequently makes the necessary
10 determination of one of his blood parameters.

However, such measurement will often be made using electrochemically functioning apparatus having a sensor on which the blood drop must be placed. Such apparatus may be owned by the patient himself, but will usually be clinic equipment used for measuring of blood samples from many different patients.
15 Unless the sensor on which the blood is to be placed is a disposable device which is disposed of each time a patient has placed his droplet of blood thereon the risk of dissimulation of infection exists when a patient is directly placing his open wounded finger with the blood drop on a sensor contaminated by blood from a previous patient.

20 This problem may be solved by using a disposable device for carrying the blood from the patient to the sensor. Such a device may be a small sponge into which the blood drop is absorbed and thereafter given off by squeezing the sponge at the sensor. This eliminates the risk as to the patient, but the handling of the free drop of blood on the patient's finger still presents a risk to the members of the clinic
25 staff, especially when they have to help the patients by squeezing a pricked finger to make the blood flow or by wiping off excessive blood from the pricked finger.

The finger pricking may be performed by using a disposable lancet unit in a tool as described in Danish patent application No. 2316/90.

It is the object of the invention to provide a blood sampler by which the
30 finger pricking and the absorption of a blood drop is obtained by using only one disposable article and without using any tool for operating the sampler, and by

which the operator of the sampler is protected against coming into contact with the blood.

This is obtained by a sampler as described in claim 1. The sampler is placed with the spacing ring of the positioning part against the skin on the spot where a sample is to be taken. The sampler is pressed against this spot by pressing the bottom of the cover. The pressure on the cover is transferred to the sampling member, and when this pressure is sufficient to overcome the locking force of the pressure releasable lock, the sampling member is pushed downwards until it abuts the base of the positioning part, the needle of the sampling member passing through the opening in the positioning part and through the skin of the patient to a depth where small blood vessels are cut and blood therefrom will pass through the needle and accumulate as a drop at the other end of the needle under the cover. During the sampling the sampling spot is well confined by the spacing ring which may be provided with an adhesive sealing bonding of the spacing ring to the sampling spot.

According to the invention the inner end of the needle may be provided with a collector with tongues which are bent outwards as petals to form a crown which may hold the blood drop preventing it from trickling down along the needle.

The cover may be made from a transparent material making it possible to inspect when sufficient blood has accumulated at the end of the needle.

Further the cover may be designed so that its opening fits narrowly over the outer side of the spacing ring. When placed fitting over the spacing ring, the cover may be used as a grip when the blood drop is to be transferred to another medium or the cover may serve as a base if the sample is to be stored for a time. At the same time the cover serves as a protection of the sharp needle end which projects from the bottom of the device when used.

In a preferred embodiment the positioning part may have the shape of a cup having the opening in its bottom and the spacing ring on the outer side of its bottom, the sampling member may have the shape of a cup fitting loosely into the positioning part with its open end in the same direction as the open end of this positioning part and may carry the needle in its bottom, and the cover may have the

shape of a cup fitting loosely with its open end into the open end of the sampling member.

The pressure releasable lock may appropriately be provided by circumferential ribs on the inner side near the opening of the positioning part and
5 on the outer side near the bottom of the sampling part; respectively, a single rib on one part engaging the space between to neighbouring ribs on the other part.

The positioning part may further have ribs on its inner side near the bottom to lock the sampling member in its position with its bottom abutting the bottom of the positioning part when pressed. Thereby reuse of the device is
10 precluded.

According to the invention the needle may be a sprinkler-needle, which is a needle being pointed without being sharp and having in its side openings communicating with a central bore. Such needles seem to cause less pain and the wounds after the pricking will heal more rapidly as no cut is made in the tissue.

15 The invention will now be described in further details with reference to the drawing, in which

Figure 1 shows a sectional view of a blood sampler placed on a sampling spot ready for being pressed by a finger,

20 Figure 2 shows the blood sampler of figure 1 with its sampling member depressed with its needle projecting into the skin, and

Figure 3 the blood sampler of figure 2 made ready for giving of the sample to a measuring station.

The blood sampler in figure 1 comprises a positioning part having the shape
25 of a cup with a bottom 1 and side walls 2, the bottom 1 being provided with a central opening 9 being surrounded by a spacing ring 3 at the outer side of the cup.

A cup shaped sampling member having a bottom 4 and side walls 5 fits loosely into the positioning part with its open end in the same direction as the open end of the
30 positioning part. The sampling member is held in a position with its bottom placed near the open end of the positioning part, this position being obtained by an internal rib 6 near the opening of the positioning part engaging a circumferential groove 7

in the outer surface of the side wall 5 of the sampling member, which groove 7 here is provided as the space between two neighbouring ribs.

A hypodermic 8 needle is secured centrally through the bottom 4 of the sampling member and has a sharp pointed end directed towards the opening 9, and an end opening into the inner of the cup shaped sampling member. At this last end the needle is extended by a plastic tube, the free end of which by slots is divided into tongues 10, which are bend outwards as petals to form a crown.

The crown is covered by a cup shaped cover 11 fitting with its open end into the open end of the cup shaped sampling member and abutting with the edge of its opening against the inner side of the bottom 4 of the sampling member.

The positioning part is placed with its space ring 3 pressed against the skin 12 of the person from whom the blood sample is to be taken. The sample is taken by pressing the bottom of the cover 11 by a finger 13. Thereby the positioning part will initially be pressed against the sampling spot whereby the skin is made ready for piercing, a pillow being formed from the skin inside the spacing ring. This has shown to lessen the sensation of pain. When the pressure has reached a sufficient magnitude the snap lock provided by the rib 6 and the groove 7 is released and the sampling member will pass down into the positioning member until its bottom 4 abuts the bottom 1 of the positioning part. Hereby the pointed end of the needle 8 is passed out through the opening 9 into to the skin 12 of the patient. The pointed end of the needle will cut some capillary blood vessels in the skin and blood will flow through the bore of the needle into the plastic tube and be collected in the crown as a drop 14 as shown in figure 2.

As further shown a circumferential rib 15 is provided on the inner side of the wall 2 near the bottom 1 of the positioning part. This rib 15 will engage the groove 7 when the sampling member is pressed down and this member will be locked in its pressed down position whereby reuse of the sampler is made impossible or at least unattractive.

The cover 11 may now be removed from its position covering the crown with the blood drop and may be fitted on the spacing ring 3. Thereby the needle which is now projecting through the bottom of the positioning part is covered to prevent anybody from being scratched by the pointed end. Further the cover acts

as a grip by which the sampler may be handled to transfer the blood drop 14 to a sensor 16 or indicator.

The cover is preferably made from transparent material to make it possible to inspect that blood is collected in the crown. If the blood does not of itself flow into the crown it may be helpful to squeeze the skin around the sampling spot, which may be done without risk of coming into contact with the blood as the sampling spot is well confined by the spacing ring 3. This confinement may be made more effective by providing an adhesive on the edge of the spacing ring making it adhere to the skin around the sampling spot.

CLAIMS

1. A blood sampler characterized in, that it comprises a positioning part having a base with an opening surrounded by a spacing ring designed to abut the skin around a sampling spot, a sampling member having a hypodermic needle and
5 being displacably mounted on the positioning part on the side of the base opposite the spacing ring, a pressure releasable lock keeping the displacable sampling member in a position with an outer sharp end of its needle directed towards the opening, a cover covering the other inner end of the needle and upon which a pressure may be exerted to release the snap lock and displace the sampling
10 member towards the positioning part to make the needle protrude through the opening and into the skin at the sampling spot.

2. A blood sampler according to claim 1, characterized in, that the inner end of the needle is provided with a collector with tongues which are bend outwards as petals to form a crown.

15 3. A blood sampler according to claim 1 or 2, characterized in, that the cover is made from a transparent material.

4. A blood sampler according to any of the preceding claims, characterized in, that the cover is cup shaped having an open end fitting narrowly over the outer side of the space ring.

20 5. A blood sampler according to any of the preceding claims, characterized in, that the positioning part has the shape of a cup having the opening in its bottom and the space ring on the outer side of its bottom, that the sampling member has the shape of a cup fitting loosely into the positioning part with its open end in the same direction as the open end of this positioning part and carrying the
25 needle in its bottom, and that the cover has the shape of a cup fitting loosely with its open end into the open end of the sampling member.

6. A blood sampler according to claim 5, characterized in, that the pressure releasable lock is provided by circumferential ribs on the inner side near the opening of the positioning part and on the outer side near the bottom of the
30 sampling part, respectively, a single rip on one part engaging the space between two neighbouring ribs on the other part

7. A blood sampler according to claim 6, **characterized** in, that the positioning part has ribs on its inner side near the bottom to lock the sampling member in its pressed down position.

8. A blood sampler according to any of the preceding claims,
s **characterized** in that the needle is a sprinkler-needle.

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Fig. 1

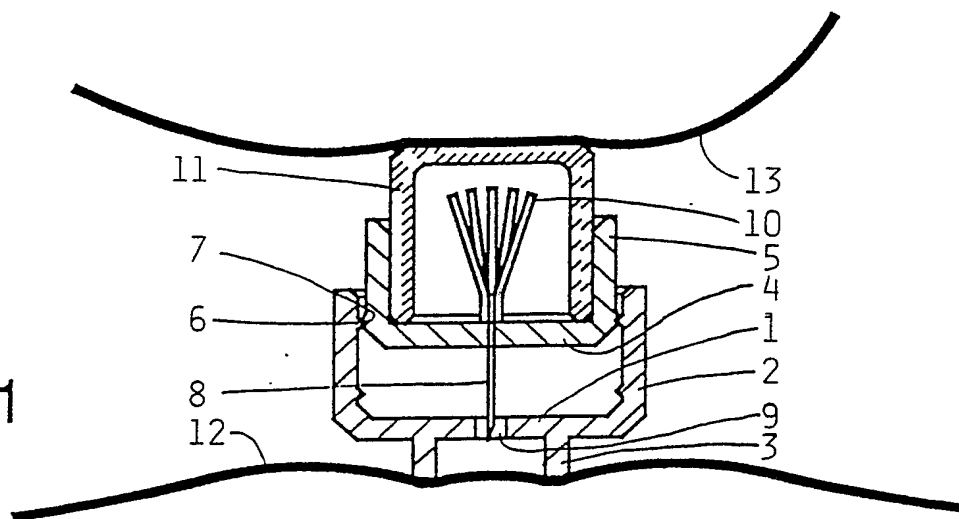


Fig. 2

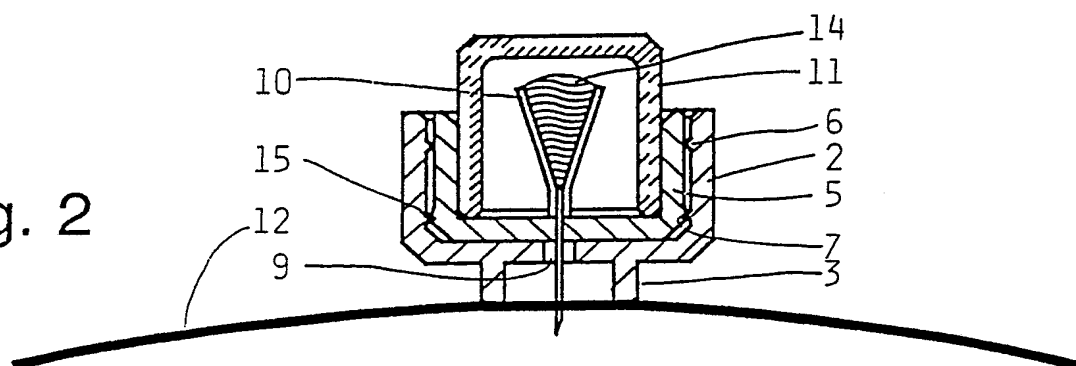
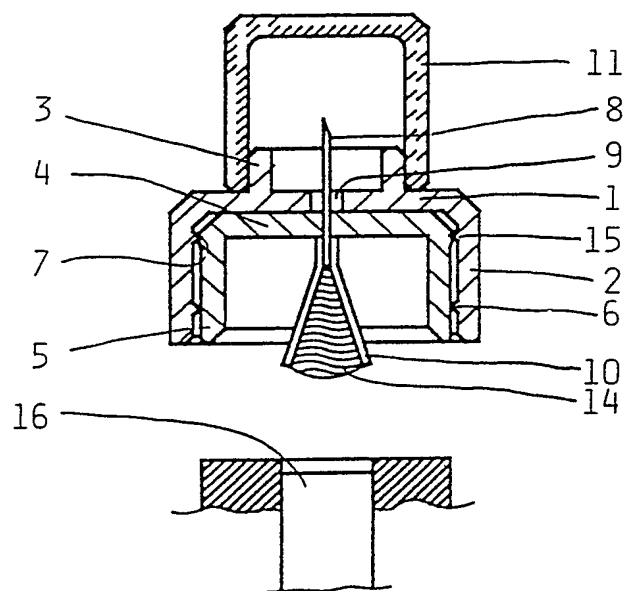



Fig. 3



INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 92/00192

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC IPC5: A 61 B 5/14, A 61 B 17/32		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC5	A 61 B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched ⁸		
SE,DK,FI,NO classes as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
Y	EP, A2, 0199484 (AUDIO BIONICS INC) 29 October 1986, see column 13, line 27 - column 15, line 17; figures 7,8 --	1
Y	US, A, 4883068 (FREDERICK L. DECHOW) 28 November 1989, see column 3, line 42 - line 68; figures 5-7 --	1
A	DE, A1, 3730469 (WAGNER, WOLFGANG) 16 June 1988, see figure 18 --	1-8
A	US, A, 4889117 (PETER A. STEVENS) 26 December 1989, see the whole document -- -----	1-8
<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 48%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
24th September 1992	30 -09- 1992	
International Searching Authority	Signature of Authorized Officer	
SWEDISH PATENT OFFICE	 ANDERS HOLMBERG	

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

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V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

- This international search report has not been established in respect of certain claim numbers because:
1. ☐ Claim numbers....., because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim numbers....., because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim numbers....., because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the the claims. It is covered by claim numbers:
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.PCT/DK 92/00192

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on 28/08/92
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
EP-A2- 0199484	86-10-29	AU-D-	5699086	86-11-05
		CA-A-	1277896	90-12-18
		US-A-	4627445	86-12-09
		US-A-	4637403	87-01-20
		WO-A-	86/05966	86-10-23
		JP-A-	61286738	86-12-17
		US-A-	4787398	88-11-29

US-A- 4883068	89-11-28	NONE		

DE-A1- 3730469	88-06-16	EP-A-	0301165	89-02-01
		DE-A-	3708031	87-11-12
		DE-A-	3713846	88-04-14

US-A- 4889117	89-12-26	NONE		